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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/837,620	04/18/2001	Donghao Chen	2685.2016-000	8051

21005 7590 04/04/2003

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EXAMINER
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GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 04/04/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/837,620	CHEN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Sharmila S. Gollamudi	1616	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 December 2002.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,4-18 and 20-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-18 and 20-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                     | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: _____.                                   |

### **DETAILED ACTION**

Receipt of the Supplementary IDS received on November 4, 2002 and Extension of Time, Supplementary IDS, and Amendment A received on December 27, 2002 is acknowledged. Claims 3 and 19 have been cancelled. Claims 1, 2, 4-18, and 20-28 are included in the prosecution of this application.

### ***Rejections***

1. Rejection of claims 3 and 4 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn.
2. Rejection of claim 1-3, 5-10, 13-19, 22-23, and 25-28 under 35 U.S.C. 102(b) as being anticipated by Edwards et al (5985309) is withdrawn.
3. Rejection of claims 1-2, 5-6, 10-14, 16-18, and 22-23 under 35 U.S.C. 102(a) as being anticipated by Bennett et al (WO 01/00312) is withdrawn.

### ***Response to Arguments***

Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection based on submitted IDS and amendments.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1, 2, 4-10, 12-14, 16-18, 20-21, 23-24 are rejected under 35**

**U.S.C. 102(b) as being anticipated by WO 97/00248.**

WO discloses spray drying pharmaceutical compositions using a drying gas with a dew point of less than 0 degrees Celsius. The inlet temperature is 40-120 degrees Celsius and the outlet temperature is 5-35 degrees Celsius. The process involves spraying a stream of air into an atomized suspension so that the solvent evaporates. The product is then collected in a cyclone. WO teaches the drying gas exhibiting a low dew point aids in the production of a substantially continuous coating. Further, the reference teaches controlling the process parameters including temperature, solvent concentration, spray drier capacity, atomizing air pressure, droplet size, and total air pressure in the system allows for a range of coats from dense, continuous, and non-porous. (Note pages 10-12).

\*Note in the absence of showing otherwise, it is the examiner's position that WO's tap density and the MMAD would be that of the instant invention's since WO teaches instant dew point and applicant claims that this dew point provides for instant particle properties.

### ***Response to Amendment***

The examiner points out that the claims recite a method of improving particulate composition; therefore WO teaches a method of improving the particulate composition by providing for a continuous coat. The newly amended recitation of "drying particles to form spray dried particles having the largest median..." is not given weight since there is no point of reference as to base what the largest MMD, lowest MMAD, and minimized tap density is. In regards to claims 17, 18, and 23 the examiner points out that the method steps are the same and the prior art particles also inherently have a MMAD and

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without a point of reference of what the "targeted" diameter/density is; therefore the prior art reads on instant claims.

**Claims 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/00248.** 97 / 39747

WO discloses spray drying pharmaceutical compositions using a drying gas with a dew point of less than 0 degrees Celsius. The inlet temperature is 40-120 degrees Celsius and the outlet temperature is 5-35 degrees Celsius. The process involves spraying a stream of air into an atomized suspension so that the solvent evaporates. The product is then collected in a cyclone. WO teaches the drying gas exhibiting a low dew point aids in the production of a substantially continuous coating. Further, the reference teaches controlling the process parameters including temperature, solvent concentration, spray drier capacity, atomizing air pressure, droplet size, and total air pressure in the system allows for a range of coats from dense, continuous, and non-porous. (Note pages 10-12).

WO does not teach the vapor pressure of the drying gas.

In the absence of showing that dew point and vapor pressure are not a function of each other, it is deemed obvious to one of ordinary skill in the art at the time the invention was that controlling the dew point of the drying gas, would also control the vapor pressure.

**Claims 1, 2, 5-18, 22-23, and 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al (5985309) in view of WO 01/23821 or vice versa.**

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Edwards et al disclose preparation of particles for inhalation. Edwards discloses the method of spray drying insulin, which is combined with lactose and DPCC, was and ethanol. The solution is spray dried with an inlet temperature of 110 degrees Celsius and an outlet temperature of 61 degrees Celsius. The tap density is .05 and the aerodynamic diameter is 1.5 microns. (Note examples, especially 9). Edwards discloses that the composition of the spray dried material and the spray drying parameters effect the aerodynamic properties of particles (col. 27, lines 12-31). Edwards teaches the inlet and outlet temperature among other factors increases porosity and surface roughness (example 2).

Edwards does not specify additional spray drying parameters, i.e. dew point/vapor pressure of the drying gas.

WO 01/23821 teaches a method of controlling evaporative drying processes. The reference teaches the parameters such as drying gas temperature, dew point, drying gas flow rate, and spray rate influence the type of final product. Further, WO teaches the control process parameters provide for a specified product quality (abstract). WO discloses that spray drying consists of four stages: atomizing the feed, spray-gas contact, drying, and separation of the dried product from the drying gas (pg. 16).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Edwards and WO since WO teaches additional parameters such as dew point effects the final product. One would be motivated to do so since both Edwards and WO teach controlling the spray drying parameters to provide for a specified product. Further one of ordinary skill in the art

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would ascertain that the dew point of the drying gas would also effect the particle diameter and density since Edwards teaches the inlet/outlet temperature effects these properties and these temperatures are related to the drying chamber's environment.

### ***Conclusion***

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on November 4, 2002 and December 27, 2002 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can normally be reached on M-F (7:30-4:30).

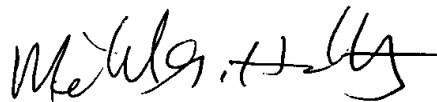
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on (703) 308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SSG



March 26, 2003



MICHAEL G. HARTLEY  
PRIMARY EXAMINER